REMARKS

Status of the Claims

Claims 1-11 are pending, with claims 4-11 having previously been withdrawn from consideration due to restriction requirement.

Claims 1-3 are rejected.

Claim 1 has been amended. No new matter has been added.

The Claimed Invention

The field of the present claimed invention relates to a device for use in an endoluminal colostomy reversal procedure. *See* Published App., ¶ [0002]. In essence, the device serves as an endoluminal colon stablizing platform for performing endoluminal surgery. The access device 10, as shown in Fig. 1, includes an elongated access member 12 with a longitudinal bore 16. *Id.*, ¶ [0025]. Access member 12 may include a slot 26 which extends from the distal end to window 24, for facilitating removal of a surgical instrument. *Id.*, ¶ [0026]. The access device 10 has a size and shape that permits it to serve several purposes: it increases "precision for locating and visualizing the zone of safety within the future ostomy site, the tube stabilizes the future anastomosis site, permits precise needle puncture, and protects the opposite luminal wall from inadvertent injury." *See* Published Application, ¶ [0027].

As one example of use in a colostomy reversal procedure, access device 10 is introduced into the stoma opening such that window 24 is arranged to face the rectal stump (denoted "r" in Fig. 6). *Id.* ¶ [0035]. A needle (e.g, needle 30 in Figs. 7 & 8) may be used to puncture the tissue to establish communication between the rectal stump "r" and healthy colon "c." *Id.* ¶ [0036]. Guide wire 32 (Fig. 8) is advanced through needle 30, window 24, longitudinal bore 16 of access device 10 and then exits the body. Access device 10 is then removed from the body with guide wire 32 remaining in place by having guide wire 32 traverse slot 26 of the access device until the two separate. *Id.* ¶ [0037]. Staple holding component 106 and anvil 108 of circular staple instrument 100 are guided into place by way of guide wire 32, as shown in Fig. 9. Once in place, the stapler is fired

to attach rectal stump "r" with the healthy colon "c", and then an opening is cut through the respective tissues to complete the communication between the stump and colon. *Id.* ¶ [0038].

To clarify that the invention is for use in colostomy procedures, Applicant amended Claim 1 to recite that the access member has an outer wall that has "a window ... being of sufficient size to pass colostomy surgical instrumentation through said window...." This amendment is supported by Published Application paragraph [0026] and Figs. 6, 8 and 9.

Rejections under U.S.C. §102(b) and §102(e)

The Examiner rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by Makower *et al.* (U.S. Patent No. 5,380,290). Makower discloses "an improved *vascular* access device... to facilitate the passage of catheters through tissue and vascular walls while eliminating the need to thread multiple components over a guidewire." *See* Makower, col. 1, lines 7-12 (emphasis added). Thus, Makower discloses a needle 14 with a sharpened tip, which has a groove (slotted opening) 26 for allowing passage of element 24. *Id.* at col. 6, lines 40-55.

The Examiner also rejected claims 1-3 under 35 U.S.C. §102(e) as being anticipated by Nash *et al.* (U.S. Patent No. 6,517,518). Nash discloses an "*intravascular* revasularization system," which allows the securing of catheter 20 (Fig. 1) into a guide-wire 24 without access to either end of the guide wire. *See* Nash, col. 4, lines 6-15 (emphasis added). Catheter 20 has a groove 28 in connected between window 34 and the distal end of the catheter.

As set forth in claim 1 of the present application, the window must be "of sufficient size to pass colostomy surgical instrumentation." As apparent, Makower and Nash are instruments solely for use with arteries and veins, i.e., the vascular system. Both disclosed devices are sized and shaped to provide vascular access, and not for use in a colostomy procedure. Neither device can be used for stabilizing the colon, and the "window" of the disclosed devices of Makower and Nash has an insufficient size and shape for permitting introduction of colostomy instrumentation. Moreover, the devices of Makower and Nash cannot be used to perform the functions of the claimed access device

which result from the size and shape of the access member and window, such as allowing a user to locate or visualize a zone of safety, stabilize the future anastomosis site, or permit precise needle puncture. The devices of Makower and Nash are not designed to perform the claimed passage of "colostomy" instrumentation limitation, and cannot be modified for use with the intestinal system. In summary, the devices of Makower and Nash have nothing to do with the claimed invention.

For these reasons, Makower and Nash do not anticipate the claimed invention. Moreover, neither reference teaches or suggests that the device can be used for a colostomy procedure since there design and function are dictated by the use with the vascular system and not intestinal system. Thus, neither reference renders the claimed invention obvious.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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